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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,223	09/12/2003	Stephen D. Pacetti	50623.330	9127

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EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT	PAPER NUMBER
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1734

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/662,223	Applicant(s) PACETTI ET AL.	
	Examiner Laura E. Edwards	Art Unit 1734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7 and 25-32 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7 and 25-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>091203</u> . | 6) <input type="checkbox"/> Other: ____ |

Specification

The amendment filed 9/12/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: paragraph 8, beginning on page 3, last four lines, --the pores have an open end and a closed end so as to provide a closed pore system on the surface of the member--.

Applicant is required to cancel the new matter in the reply to this Office Action.

The disclosure is objected to because of the following informality: on page 1, Applicants need to update the history of the application with --U.S. Patent No. 6,673,154--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-7, 25, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. The specification as originally filed failed to teach or suggest a stent support member having pores "wherein the pores have an open end and a closed end so as to provide a closed pore system on the surface of the member" as now recited in claim 1, lines 5-6.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-7, and 25-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,673,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the present application and patent disclose a single inventive concept to an apparatus for supporting a stent comprising at least one member for supporting the stent and the at least one member being porous or absorbent to receiving at least a partial amount of coating substance applied to the stent during coating.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4, 5, and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Frisch (US 4,906,423).

Frisch teaches a support mandrel for manufacturing a prosthetic device or stent comprising a member including a plurality of pores disposed on a surface of the member, the pores capable of receiving the coating substance during a coating process wherein the pores have an open end and a closed end so as to provide a closed pore system on the surface of the member (see col. 3, lines 60-65 and col. 4, lines 23-30). Applicants' intended use of the support member with the stent during coating is an intended use or process limitation that has been considered but given no patentable weight.

Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Parsons et al (US 6,521,284).

Parsons et al teach a support mandrel for manufacturing a prosthetic device or stent comprising a support member or mandrel including a plurality of pores disposed on a surface of the member, the pores capable of receiving the coating substance (i.e., fluid including gas) during a coating process wherein the pores have an open end and a closed end so as to provide a closed pore system on the surface of the member (see col. 5, lines 10-20). Applicants' intended use of the support member with the stent during coating is an intended use or process limitation that has been considered but given no patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 2, 6, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch US 4,906,423).

Frisch teaches a mandrel for supporting a prosthetic device as mentioned above. Even though Frisch teaches that the pore size and density of the porous surface is controlled by cell size and density of foam material employed (see col. 3, lines 67+ to col. 4, lines 1-22), Frisch is silent concerning the pore diameter of .2 to 50 microns. However, one of ordinary skill in the art would determine via routine experimentation the appropriate foam material to use having a desired pore diameter in accordance with the medical device being produced and the amount of material sought to be absorbed on the support mandrel.

Claims 2, 6, 7, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al (US 6,521,284).

Parsons et al teach a support mandrel for manufacturing a prosthetic device or stent as mentioned above. Even though Parsons et al teach that the mandrel may have pores of any size, Parsons et al fail to teach or suggest the mandrel having a pores of a diameter of 0.2 to 50 microns. However, one of ordinary skill in the art would determine via routine experimentation the appropriate pore size including diameter in accordance with the medical device being produced and the amount of material sought to be retained on the support mandrel.

With respect to the types of materials (polymer, metal or ceramic) used to make the mandrel, it is within the purview of one of ordinary skill in the art to utilize any known polymer, metal, and/or ceramic material from which to make the mandrel in so long as such materials do

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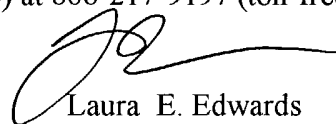
not destroy, degrade, or interactive in any negative manner with the stent and the material used to coat the stent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura E. Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Laura E. Edwards
Primary Examiner
Art Unit 1734

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September 6, 2004